CALIFORNIA DEPARTMENT OF HEALTH SERVICES SMALLPOX VACCINATION PROGRAM

NATIONAL AND CALIFORNIA VACCINATION CONTRAINDICATIONS POLICY February 7, 2003

GENERAL GUIDANCE

The primary concern of the California Department of Health Services (CDHS) is to conduct the smallpox vaccination program with the highest degree of safety. The following general principles of screening should apply.

- Borderline or unclear circumstances should be interpreted conservatively as a contraindication to vaccination. In any case where doubt exists, do not vaccinate.
- Any vaccinator may withhold vaccination if he or she is uncomfortable with the ability of the proposed vaccine recipient to properly care for the vaccination site or protect third parties from inadvertent infection. The vaccinator is not obliged to vaccinate anyone who demands vaccination despite contraindications in themselves or a family member.

Local Health Departments who are participating in the CDHS voluntary smallpox preparedness vaccination program will follow current Advisory Committee on Immunization Practice (ACIP) and Centers for Disease Control and Prevention (CDC) contraindications for smallpox vaccination.

ACIP/CDC CONTRAINDICATIONS FOR VACINEES AND HOUSEHOLD CONTACTS

Smallpox vaccination in the pre-outbreak setting is contraindicated for persons who have the following conditions or have a household contact with the following conditions. For the purpose of screening for contraindications, "household contacts" should be considered to include persons with prolonged intimate contact with the potential vaccinee, including the potential for direct contact with the vaccination site, e.g., sexual contacts.

Smallpox vaccine should not be administered to persons with a history of
eczema or atopic dermatitis, irrespective of disease severity or activity or a
household contact with these conditions. This applies even if no rash is currently
present. The terms eczema and atopic dermatitis often are used
interchangeably. The criteria to suspecting these conditions are a history of an
itchy red rash that comes and goes. Sometimes this recurrence is in response to
a known stimulus, but often the rash can reappear for no apparent reason. A
defect in cell-mediated immunity underlies these conditions, and this defect is
present even when there is no rash.

- Persons with other active acute, chronic, or exfoliative conditions that disrupt the
 epidermis or cause fissuring of the skin (e.g., burns, impetigo, varicella zoster,
 herpes, severe acne, psoriasis, and other conditions resulting in open skin
 lesions) are at higher risk for clinically significant inadvertent inoculation and
 should not be vaccinated until the condition resolves. A history of herpes simplex
 or shingles in the past is not a contraindication to vaccination, as long as no
 lesions or other contraindications are present. Smallpox vaccine should not be
 administered to persons whose household contacts have any of these active skin
 conditions. Darier disease (keratosis follicularis) is a contraindication in a
 potential vaccinee and a contraindication if a household contact has active
 disease.
- Persons who are immunocompromised as a result of human immunodeficiency virus or acquired immunodeficiency syndrome (HIV, AIDS), leukemia, lymphoma, generalized malignancy, solid organ transplantation, cellular or humoral immunodeficiencies, or therapy with alkylating agents, antimetabolites, radiation, or high-dose corticosteroids. Autoimmune disorders, including systemic lupus erythematosis that is moderate to severe, or treated with immunosuppressants may also be associated with immunodeficiency. Cancer that has been cured or is in remission is not necessarily a contraindication as long as the person in question is not on immunosuppressive medication and has no other contraindications. A household contact with any of these conditions is also a contraindication.
- Any person on chronic maintenance steroids should be screened carefully.
 People on inhaled steroids for asthma are not contraindicated. However, people on a short burst of steroids for an acute condition should probably forgo vaccination until the illness has resolved, less because of the steroids than because of the acute illness.
- Pregnant women or women who desire to become pregnant in the 28 days after vaccination, or persons with such household contacts, should not receive smallpox vaccine. Sexually active female vaccinees of childbearing age should use a reliable form of birth control until the vaccination scab separates.

ACIP/CDC CONTRAINDICATIONS THAT APPLY ONLY TO VACCINATION CANDIDATES – NOT CLOSE CONTACTS

- Breastfeeding women should not receive the vaccination, because it is not known whether the virus is excreted in breast milk.
- Any moderate to severe acute illness in an otherwise healthy individual is a contraindication to vaccination until the acute illness has resolved.

- Asthma, *per se*, is not a contraindication to vaccination provided no other contraindication is present. Some patients with asthma have associated atopy, which is the reason this condition is solicited in the screening document.
- Severe, life-threatening allergy to any vaccine component, such as polymixin B, streptomycin, chlortetracycline, or neomycin is a contraindication to vaccination. However, a household contact with these allergies is not a contraindication.
- Inflammatory conditions of the eye requiring the use of ophthalmic topical steroids. Vaccination can be done when the inflammation has resolved and steroids discontinued.
- People under 18 years of age should not receive vaccine in this non-emergency program. CDC recommends 65 years of age as an upper age limit for this program.

CALIFORNIA POLICY FOR PERSON LIVING WITH A CHILD UNDER 12 MONTHS OF AGE

The CDHS policy is to defer vaccination of candidates who have an infant less than 1 year of age in the household until the child is one year of age.

ACIP and CDC do not consider the presence of an adolescent or child (including an infant) in the vaccine recipient's household to be a contraindication to vaccination. Data suggest that the risk of serious complications of transmission from an adult to a child is extremely small and this transmission is preventable using good hygiene and vaccination site care. Nonetheless, ACIP recognizes that some programs may defer vaccination of household contacts of infants less than 1 year of age because there is data suggesting a higher risk of adverse events among primary vaccine recipients in this age group, compared with that among older children, especially encephalitis. In addition, breast-feeding an infant is a contraindication Because of these concerns, the CDHS policy is to defer vaccination of candidates who have an infant less than one year of age.

POLICY UPDATES

This list of contraindications will change over time, as we gain experience with the vaccination both nationally and locally. Additional experience, new research, and recommendations by professional societies based on review of past experience may also result in further clarification of the contraindications or added ones.

In the event of an actual smallpox outbreak, this list would change considerably. Furthermore, for individuals directly exposed to smallpox, there are no contraindications to vaccination.

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February 21, 2003

RE: Patient advisory for additional vaccine restriction

It is the policy of the California Department of Health Services not to vaccinate anyone with a child under one year of age in their household. This is to avoid any possibility of accidental contact transmission of the vaccine to your child. During this voluntary vaccination program, we want to minimize any risk of adverse reactions.

The reasons for this policy are:

- 1. Children, especially those under one year of age, have a higher risk of serious adverse events from smallpox vaccine.
- 2. There is very close physical contact between child and adult during bottle feeding.
- 3. When the vaccine was given routinely to all children, it was not given to those under one year of age.

You may be vaccinated after your child reaches one year of age.

